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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/966,447	09/28/2001	David Christian Lentz	CRD-0957	2148

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EXAMINER

RYCKMAN, MELISSA K

ART UNIT	PAPER NUMBER
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3773

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 09/966,447	Applicant(s) LENTZ ET AL.	
	Examiner MELISSA RYCKMAN	Art Unit 3773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE ____ MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-34 is/are pending in the application.
- 4a) Of the above claim(s) 18-34 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-17 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

This office action is in response to claims filed 6/16/08.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1 and 3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sakura, Jr. (U.S. Patent No. 4,214,587) in view of Swanson et al. (U.S. Patent No. 6,113,612).

Sakura teaches a device for joining substantially tubular organs in a living organism, comprising: an anastomosis device for connecting a graft vessel to a target vessel such that the two vessels are in fluid communication (Fig. 7), the anastomosis device including a fastening flange (11) and a plurality of staples (distal portion of 12) connected to the fastening flange and having sharpened ends (Fig. 1) with barbs (sharp tips are barbs), the fastening flange comprising a single wire ring structure having a substantially sinusoidally shaped (Fig. 2) configuration for reduced profile delivery (capable of being reduced because of the material, the distance from the top of one curve to the other curve is capable of shortening upon delivery) and configured to have a substantially flat profile upon deployment (Fig. 4, from this view 11 has a flat profile)

and the plurality of staples (distal portion of 12) being configured to spring from a restraint position (Fig. 6) to a position substantially perpendicular to the ring structure and finally to an inverted loop position through the graft vessel and target vessel (capable of being bent in the manner as described), the plurality of staples (distal portion of 12) extending from the wire ring (Fig. 12) structure in the same direction (both extending in the up direction) as the substantially sinusoidally shaped configuration (Fig. 1) and extending substantially beyond the wire ring for inversion (Fig. 4).

Sakura is silent regarding a biocompatible vehicle affixed to the device, however Swanson teaches an anastomosis device wherein the device includes a biocompatible vehicle (522, 530) being made from polymer materials for carrying drugs to facilitate healing and or sealing (Column 13, proximate lines 3-24). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Kaster with a biocompatible vehicle including a therapeutic agent as taught by Swanson in order to carry drugs to facilitate healing and or sealing of the anastomosis site.

Claims 4-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Sakura and Swanson et al.

Although the combination of Sakura and Swanson et al. do not disclose the anastomosis device comprising the polymeric matrix and drugs as claimed, the polymeric matrix and drugs as claimed are well known in the art that are provided on a stent or an anastomosis device in order to deliver drug for treating and healing or preventing restenosis at an implantation site. Therefore, it would have been obvious to

one having ordinary skill in the art at the time the invention was made to employ the polymeric matrix and drugs as claimed in order to effectively deliver the drug for treating, healing and preventing restenosis at an implantation site.

Regarding to the specific weight percentage of polymers of a copolymer as claimed, it is well known in the art to make a copolymer out of various percentages by weight in order to provide a polymer matrix with a desire property/characteristic. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to varying the property/characteristic of the polymeric matrix by varying the percentages by weight of each residue in order to maximize the property/characteristic of polymeric matrix for use in certain drug application.

Response to Arguments

Applicant's arguments filed 6/16/08 have been fully considered but they are not persuasive. The applicant generally argues:

- Sawanson does not teach “the wire ring is configured to flatten upon deployment and the staples extend substantially beyond the ring so that they may be everted.”

The examiners position is this limitation is not in the claims, a flat profile as stated in the claims is not the same as the wire ring is configured to flatten.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELISSA RYCKMAN whose telephone number is (571)272-9969. The examiner can normally be reached on Monday thru Friday 7:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571)-272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3773

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MKR

/Melissa Ryckman/
Examiner, Art Unit 3773

/(Jackie) Tan-Uyen T. Ho/
Supervisory Patent Examiner, Art Unit 3773